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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/654,227	08/31/00	HEIL W	PLOVIN-1-A

EXAMINER	
RAHAR, M	
ART UNIT	**PAPER NUMBER**
1617	10

DATE MAILED: 09/13/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/654,227	HEIL ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 23-25 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's response to the restriction requirement submitted June 13, 2001 is acknowledged.

Applicant's election with traverse of Group I, claims 1-22 in Paper No. 9 submitted August 16, 2001 is acknowledged. Applicant's traversal on the ground that no burden of search has been established. Applicant's argument in this regard has been considered but is not found persuasive.

As shown in the restriction requirement of May 14, 2001 the inventions in Groups II-IV are unrelated since they have different functions. Moreover, Group I, although related to the other three groups, is distinct from them, see restriction requirement, page 2 particularly. Each group requires a different field of search and the search for all groups is therefore an undue burden on the office. Note that the search is not limited to patent files.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 9

Claims 1-22 are herein examined on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: The use of parenthetical expressions "(drospirenone)" and "(ethinyl estrsdiol)" in the claims is considered informal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6, 13, 16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3, 5, 6, 13, 16 and 21 recite the broad recitations "from about 2.5 mg to about 3.5 mg" in claim 3; "from about 0,015 mg to about 0.04 mg" in claim 5; "from about 3.0 to about 3.5 mg" and "from about 0.015 to about 0.03 mg" in claim 6; "such as 2-4" in claim 13; "from about 2.5 mg to about 3.5 mg" and "from about 0.015 mg to about 0.04 mg"in claim 16; "from about 2.5 to about 3.5 mg" and "from about 0.015 to about 0.04 mg" in claim 21 respectively and the claims also recite "in particular about 3 mg" in claim 3; "in particular from about 0.02 mg to about 0.03 mg" in claim 5; "in particular...about 3.0 mg" and "in particular...about 0.03 mg" in claim 6; "in particular 2 or 3 times" in claim 13;

""in particular about 3 mg" and "in particular from about 0.015 mg to about 0.03 mg" in claim 16; and "in particular about 3 mg" and "in particular from about 0.02 mg to about 0.03 mg" in claim 21 which are the narrower statements of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3, 5, 7, 10-12, 16-17 rejected under 35 U.S.C. 102(b) as being anticipated by Gast (WO 98/04269).

Gast (WO 98/04269) discloses a combination composition comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol, and pharmaceutically acceptable carriers and excipients, see page 9, lines 19-33 and claim 1. Gast (WO 98/04269) also teaches a contraceptive kit adapted for daily oral administration which comprises 28 separate dosage units with 3-5 dosage units being a non-contraceptive placebo, see page 10, lines 15-24 in particular.

Claims 18-20 rejected under 35 U.S.C. 102(b) as being anticipated by Gast (WO 98/04267).

Gast (WO 98/04267) discloses a combination composition and pharmaceutically acceptable carriers and excipients comprising 23-25 daily dosage units comprising 250

microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol and 3-5 dosage units comprising 5 to 15 micrograms of ethinyl estradiol, see claim 1 and page 9, lines 15-24 in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,4, 8-9 and 13-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Gast (WO 98/04269).

Gast (WO 98/04269) teaches a combination composition comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol, and pharmaceutically acceptable carriers and excipients,see page 9, lines 19-33 and claim 1. Gast (WO 98/04269) also teaches a contraceptive kit adapted for daily oral administration which comprises 28 separate dosage units with 3-5 dosage units being a non-contraceptive placebo, see page 10, lines 15-24 in particular.

Gast (WO 98/04269) does not teach drospirenone or ethinyl estradiol in micronized form, neither does it explicitly teach the release time of the actives or a kit containing 28 dosage units all containing drospirenone and ethinyl estrsdiol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ drospirenone or ethinyl estradiol in micronized form. It would have also been obvious to include 28 dosage units all containing drospirenone and ethinyl estrsdiol in Gast's kit.

One of ordinary skill in the art would have been motivated to employ known pharmaceutical actives in micronized form because variations or optimizations of the dosage regimen of compounds well known to be administered together in combination, are considered within the skill of the artisan.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gast (WO 98/04267).

Gast (WO 98/04267) discloses a combination composition and pharmaceutically acceptable carriers and excipients comprising 23-25 daily dosage units comprising 250 microgram to 4 mg of drospirenone and 10-20 microgram of ethinyl estrsdiol and 3-5 dosage units comprising 5 to 15 micrograms of ethinyl estradiol, see claim 1 and page 9, lines 15-24 in particular.

Gast (WO 98/04267) does not teach drospirenone or ethinyl estradiol in micronized form.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ drospirenone or ethinyl estradiol in micronized form.

One of ordinary skill in the art would have been motivated to employ known pharmaceutical actives in micronized form because variations of the dosage form of known pharmaceutical actives are considered within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
September 6, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200